IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC. and UNITED STATES VAPING ASSOCIATION, INC.,	§	
Plaintiffs,	§	
	§	Civil Case No. 1:19-cv-531-LG-JCG
v.	§	
FOOD AND DRUG ADMINISTRATION; NORMAN E. "NED" SHARPLESS, M.D., in his official capacity as Acting Commissioner of Food and Drugs; and ALEX M. AZAR, II, in his official capacity as Secretary of Health and Human Services,	§	DECLARATORY AND INJUNCTIVE RELIEF REQUESTED
Defendants.	§	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT
OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs file this reply memorandum in support of their motion for a preliminary injunction. Plaintiffs will respond separately to the Defendants' motion to dismiss.

ARGUMENT

I. Plaintiffs Are Likely to Succeed in Establishing that TCA § 387a(b) Is Invalid.

Plaintiffs have explained that the TCA's deeming provision must be invalidated because it sets forth no standard or policy to guide the Executive's discretion as to which "tobacco products" shall be deemed and which shall remain unregulated. *See Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Defendants' response does not undermine this conclusion. Plaintiffs address the points in turn.

a. TCA § 387a(b) is likely to be found unconstitutional.

Seven years *after* the Court referred to the requisite "intelligible principle" in *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928), Section 9(c) of the National Industrial Recovery Act (NIRA) was declared unconstitutional in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Congress had defined a narrow subject matter (oil produced in excess of state-law allowances), and "authorized" the President "to prohibit [its] transportation in interstate or foreign commerce," at his discretion. This was what the Defendants might describe as a "limited, binary" choice, just like the choice whether to "deem" tobacco products to be subject to the TCA. *See Defs' mem.* at 35 ("21 U.S.C. § 387a(b) does not empower the FDA to impose additional obligations—it authorizes only a determination whether certain 'tobacco products' should be required to comply with all of the TCA's provisions, or instead should be entirely exempt."). *Panama Refining* held that "the question whether that transportation shall be prohibited by law is obviously one of legislative policy," and proceeded, as the plurality in *Gundy v. United*

States describes the test, to "figure out…what instructions [the statute] provides" to guide the delegated decision. 139 S. Ct. 2116, 2123 (2019). Section 9(c) was an unconstitutional delegation because it did "not state whether or in what circumstances or under what conditions the President is to prohibit the transportation" of hot oil, "establish[ed] no criterion to govern the President's course," and "require[d no] finding by the President as a condition of his action." *Panama Refining*, 293 U.S. at 415. Instead, it gave him "an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit." *Id.* Just as in *Panama Refining*, the choice whether to deem any given product or not is a legislative choice for which Congress has provided no policy, standard, or even factors for consideration.

b. Defendants' arguments are unpersuasive.

Defendants' various efforts to escape the holding of *Panama Refining* are unavailing.

i. The fact that the Secretary's deeming authority operates only within the field of "tobacco products" does not supply an "intelligible principle" guiding the decision whether any particular product shall be regulated or unregulated.

First, Defendants attempt to ignore the fact that NIRA § 9(c) conferred discretion within only a narrowly-defined subject area. *Defs' Mem.* at 37-38. *Panama Refining* began its analysis by observing that "[t]he subject to which this authority relates is defined. It is the transportation in interstate and foreign commerce of petroleum and petroleum products which are produced…in excess of the amount permitted by state authority." 293 U.S. at 414-15. Thus, the fact that the deeming provision confers discretion only with respect to the field of "tobacco products" does not save the TCA any more than the fact that NIRA 9(c) was strictly circumscribed to a subset of petroleum products withdrawn in violation of state law. Plaintiffs predicted that the Defendants would "argue that the mere fact that this authority operates only within the field of 'tobacco products' is sufficient to save the statute," and explained why that argument is precluded by

Panama Refining and *Gundy*. *Plfs' mem.* at 43-44. The fact that Defendants have *still* failed to grapple with the actual holding of *Panama Refining* is a reflection of the merits of Plaintiffs' argument.

Rather than directly address *Panama Refining*, Defendants characterize *United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981), as an example of a failed nondelegation challenge "to a statute that, just like the [TCA], imposed fixed statutory requirements with respect to a congressionally defined category, *but gave the Executive Branch discretion to determine the applicability of the statute to products falling within that category*[.]" *Defs' Mem.* at 27 (emphasis added). Not so. *Womack* considered a statute that prohibited "engag[ing] in the business of importing, manufacturing, or dealing in explosive materials" without a license, defined "explosive materials" to mean "explosives, blasting agents, and detonators," and defined "explosives" as follows:

> any chemical compound mixture, or device, the primary or common purpose of which is to function by explosion; the term includes, but is not limited to, dynamite and other high explosives, black powder, pellet powder, initiating explosives, detonators, safety fuses, squibs, detonating cord, igniter cord, and igniters. The Secretary shall publish and revise at least annually in the Federal Register a list of these and any additional explosives which he determines to be within the coverage of this chapter.

654 F.2d at 1036.

Womack thus addressed a question materially distinct from the TCA. The federal statute in *Womack* applied the offense to *all* "explosives," and there was no suggestion that the Attorney General was authorized to (i) find that something fit the definition of "explosive," but then (ii) decline to list it in his discretion.

ii. The fact that the TCA lays out the restrictions applicable to products subjected to it does not substitute for the lack of any standard to guide the Secretary in deciding whether these restrictions will apply.

Defendants place much emphasis on the fact that Congress has articulated exactly what restrictions and requirements apply to any deemed tobacco products once they are subjected to the TCA. *Defs' mem.* at 26-27, 29. This is true, but it does not remedy the lack of any standards to guide the Secretary's decision whether to subject any product to these restrictions or not.

Plaintiffs wrote in their memorandum that "the authority to decide the factors or circumstances under which a given activity or product shall be subjected to a certain field of regulation is quintessentially one of legislative policy." *Plfs. Mem.* at 39. This is a fundamental principle consistently reflected in nondelegation jurisprudence. *Field v. Clark* rejected the argument that the President's authority to issue a proclamation, upon finding the existence of certain predicate facts, violated the principle, because "Legislative power was exercised when *congress* declared that the suspension should take effect *upon a named contingency*." 143 U.S. at 693. In 1941, the Court wrote that "[t]he adoption of the declared policy by Congress *and its definition of the circumstances in which its command is to be effective*, constitute the performance, in the constitutional sense, of the legislation function." *Opp Cotton Mills v. Admin. of Wage and Hour Division of Dep't of Labor*, 312 U.S. 126, 144 (1941) (emphasis added). *Yakus v. United States*, 321 U.S. 414 (1944), noted that "[t]he essentials of the legislative function … are preserved when Congress has specified the basic conditions of fact upon whose existence or occurrence, ascertained from relevant data by a designated administrative agency, it directs that its statutory command shall be effective." Commensurate with this principle, *Panama Refining* held that "the question whether … transportation [of hot oil] shall be prohibited" or not "is obviously one of legislative policy," and struck down the statute because Congress had failed to provide any relevant guidance. 293 U.S. at 415. By failing to state any standard, Congress left to the Executive the

legislative authority to determine whether or under what circumstances any given tobacco product should be regulated.

This deficiency is not rectified by the fact that Congress has written a detailed code that shall apply to any product the Secretary decides to deem. For example, in *Touby v. United States*, the plaintiff challenged § 201(h) of the Controlled Substances Act (CSA), granting authority to the Attorney General to temporarily assign substances presenting an "imminent hazard to the public safety" to one of the five categories (or "schedules") of substances under the CSA. 500 U.S. 160, 160-165 (1991). The CSA provides detailed regulations to the manufacture, possession, and distribution of substances, varying according to the schedule. *Id.* at 162. The nondelegation challenge was not answered merely by reference to the fact that, *once scheduled*, a detailed statutory scheme applied to the substance. Instead, the Court examined whether Congress had provided sufficient guidance to "meaningfully constrain" the Attorney General's discretion to temporarily schedule the substance in the first place. *Id.* at 166. Specifically, the statute was upheld because it required the Attorney General to "find that [temporarily scheduling a substance] is 'necessary to avoid an imminent hazard to the public safety,'" he was "required to consider three [identified] factors," *and* "must satisfy the requirements of § 202(b)," which "identifies the criteria for adding a substance to each of the five schedules." *Id.* at 166-67.

Here, Congress left the legislative policy choices entirely to the Executive, who is free to deem, or not to deem, any given product according to any criteria or considerations he or she thinks relevant or persuasive.

iii. Congress's broad statements of purpose do not provide meaningful policy guidance.

The FDA writes that "[t]he standards of the [challenged] statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual

background and the statutory context in which the standards appear." *Defs' Mem.* at 30 (quoting *Womack*, 654 F.2d at 1037 (citing *American Power & Light*, 329 U.S. at 105)). While this is true, it does not save the TCA's deeming provision, for three reasons. First, there is *no statutory standard* to be fleshed out with reference to the general declarations of purpose. Second, the declarations of purpose are both amorphous and self-contradictory, as some purposes are in direct tension with other purposes. Third, even if one *could* discern a guiding principle from the statements of purpose, reading the statute as a whole requires recognizing that Congress limited the TCA's application to a subset of tobacco products, precluding any attempt to derive "meaningful content" from the prefatory section of the Act alone.

The Defendants' primary authority for this point, *American Power & Light Co. v. SEC*, 329 U.S. 90 (1946), is far afield. While broadly stated, the relevant provision of the Public Utility Holding Company Act of 1935 imposed the kind of substantive standard that is entirely lacking in § 387a(b). Section 11(b)(2) of that Act "provide[d] that the Commission shall act so as to ensure that the corporate structure or continued existence of any company in a particular holding company system does not 'unduly or unnecessarily complicate the structure' or 'unfairly or inequitably distribute voting power among security holders.'" *American Power & Light*, 329 U.S. at 104. The Court held that "even standing alone, standards in terms of unduly complicated corporate structures and inequitable distribution of voting power cannot be said to be utterly without meaning, especially to those familiar with corporate realities." *Id.* It was then the Court provided the language Defendants here rely upon, stating that "*these standards* need not be tested in isolation." *Id.* (emphasis added). The Act's other provisions provided a consistent framework fleshing out what Congress had in mind by "unduly or unnecessarily complicated structures" and inequitable distribution of voting power, including not just the "general policy declarations," but

also the "standards for new security issues set forth in s 7, the conditions for acquisitions of properties and securities prescribed in s 10, and the nature of the inquiries contemplated by s 11(a)—a veritable code of rules … for the Commission to follow in giving effect to the standards of s 11(b)(2)." *Id.* at 105.

Here, by contrast, the TCA provides *no* standard to guide the Secretary's deeming decisions. That fatal deficiency places this case under the controlling authority of *Panama Refining*, which directly rejected the government's attempt to salvage a standardless statute by importing some broadly-stated principle cherry-picked from the act's prefatory section of "diverse objectives." 293 U.S. at 417-18. The Court observed that NIRA's "general outline of policy contains nothing as to the circumstances or conditions in which transportation of petroleum or petroleum products should be prohibited," and "[t]he Congress did not say that transportation of that oil was 'unfair competition,'" or "declare in what circumstances that transportation should be forbidden, or require the President to make any determination as to any facts or circumstances." *Id.* at 418. While prohibiting the transportation of hot oil might have furthered some of the policy aims identified in the law (*e.g.*, "eliminat[ing] unfair competitive practices" and "conserv[ing] natural resources" during a wartime emergency), it might have hindered other purposes (including "remov[ing] obstructions to the free flow of interstate and foreign commerce which tend to diminish the amount thereof"). 293 U.S. at 418. The statute delegated legislative power because "[a]mong the various and diverse objectives broadly stated, the President was not required to choose" which policy to pursue. *Id.*[1]

[1] Here, FDA cannot claim that its heavy-handed, indiscriminate regulation of ENDS is clearly supported by the TCA's purpose statements when such regulation threatens serious damage to Congress's aim of "promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases[.]" Pub. L. No. 111-31 § 3(9). Even current and former FDA officials have acknowledged and praised the potential public health benefits of vaping technology. Amazingly, FDA's unilateral plans to regulate ENDS pursuant to the Deeming Rule will seriously hamper the development and accessibility of the technology most prevalent among adult former smokers (open-system

Lastly, and perhaps most importantly, even if one *could* discern some kind of workable principle from the TCA's prefatory statements of purpose, FDA cannot ignore the fact that, despite these general statements, Congress limited the application of the TCA to cigarettes and smokeless tobacco, and failed to outline why or when the Secretary should deem anything else. The TCA defined "tobacco products" broadly, so that it encompassed a whole range of products in widespread use in 2009. These included cigarettes, cigars (of varying classifications), pipe tobacco, smokeless tobacco, waterpipe tobacco (hookah), and others. Congress's careful circumscription of the TCA, however, reflects a legislative determination to leave many types of tobacco products entirely unregulated.

The *Gundy* plurality supports Plaintiffs, not Defendants, on this point. The relevant provision of SORNA provided that "[t]he Attorney General shall have the authority to specify the applicability of the requirements of this subchapter to sex offenders convicted before the enactment of this chapter[.]" *Gundy*, 139 S. Ct. at 2122. The plurality began by explaining that the Court in *Reynolds v. United States*, 565 U.S. 432 (2012), had "already interpreted [the statute] to … *require* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*," *id.* at 2123 (citing *Reynolds*, 565 U.S. at 442-43) (italics added). After *Reynolds*, the plurality wrote, "'[s]pecify the applicability' … does not mean 'specify *whether* to apply SORNA' to pre-Act offenders at all, even though everything else in the Act commands their coverage. The phrase instead means 'specify *how* to apply SORNA' to pre-Act offenders if transitional difficulties require some delay." *Id.* at 2128. The plurality went on to express its agreement with *Reynolds*'

devices), while at the same time providing a market advantage to Juul, which is not only the company that has nearly single-handedly cornered the child-vaping market with slick devices easily stowed in a schoolchild's pocket, but is uniquely positioned to capture more market share after the mere specter of PMTA requirements forces all others out of the market.

interpretation, and thus identified the delegation question as: "Did Congress make an impermissible delegation when it instructed the Attorney General to apply SORNA's registration requirements to pre-Act offenders as soon as feasible?" *Id.* at 2129. Unlike with SORNA, there is no way to read the deeming provision as if it *required* the Secretary to deem any particular product, or category of products, to be subject to the requirements of the TCA. Instead, § 387a(b) codifies Congress' *deliberate choice* to *strictly limit* the application of the TCA, but simultaneously punt to the Executive the question whether it shall be extended to other products, without establishing a policy.

Congress's deliberate limitation of the TCA's reach (and standardless delegation) similarly precludes the FDA from seeking support in any other provisions that it has cited. So, while § 393(b)(1) authorizes the FDA to "tak[e] appropriate action on the marketing of *regulated* products in a timely manner," *see Defs. Mem.* at 33, 35, 45 (italics added), this authority is predicated on the FDA's unilateral decision to regulate ENDS in the first place.

iv. The constitutional requirement of an intelligible principle is not ignored in a complex or "fast-moving industry."

Lastly, it goes without saying that enforcing the basic principles of the Constitution will not prevent "regulators [from] keep[ing] up with technological changes in this fast-moving industry." *Defs' Mem.* at 34. Regulation of tobacco products and/or ENDS is certainly no more complex than keeping up with "designer" narcotics deliberately modified by traffickers attempting to avoid the Controlled Substances Act's list of scheduled drugs, for which Congress was able to write quite detailed constraints on the Attorney General's temporary scheduling authority commensurate with the nondelegation principle. *Touby*, 500 U.S. at 162-67. Another permissible approach would be to charge the FDA with the duty to monitor the industry for the emergence of certain triggering conditions as a prerequisite to deeming a product, similar to how Congress has

handled trade issues, as in *Field v. Clark*, 143 U.S. 649 (1892) (discussed in *Plfs' Mem.* at 37). What is not permissible is the standardless delegation in the current deeming provision.

* * *

In the end, the FDA's response never frontally addresses the nondelegation issue. Struggling to articulate a workable standard that is nowhere to be found in the TCA, Defendants write that "the general policy that Congress adopted—that is, promoting the public health through efficient enforcement of the statutory requirements that *Congress imposed upon the tobacco industry*—is more than sufficient[.]" *Defs' Mem.* at 34 (emphasis added). This simply avoids the ultimate question, as *Congress* only imposed the TCA on cigarettes and smokeless tobacco. It was (and remains) up to the FDA to apply whatever criteria it wants to determine what *other* tobacco products shall be regulated.

Unable to identify any actual standard governing its deeming discretion, FDA's fallback seems to be that the constitutional question can be waved away by the suggestion that subjecting ENDS to the TCA would pass muster under an appropriately limited (hypothetical) version of the TCA. *Defs' Mem.* at 45 ("[S]urely at least *some* FDA oversight of *some* of these potentially harmful products is in the public interest—at least with respect to the most dangerous and youth-friendly products and marketing practices.") (italics in original). This reflects a misapprehension of the nature of a separation of powers challenge. The FDA cannot rescue a standardless statute from scrutiny by demonstrating that the agency has, or will, interpret or apply its authority only within constitutional bounds. *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 472-73 (2001); *see id.* at 437 ("Whether the statute delegates legislative power is a question for the courts, and an agency's voluntary self-denial has no bearing upon the answer."); *Collins v. Mnuchin*, 2019 WL 4233612, at *21, 21 n.224 (5th Cir. 2019) (en banc).

Defendants have had an opportunity to respond fully to Plaintiffs' argument, and they have not cited any case rejecting a nondelegation challenge to a statute that is devoid of a standard. As Plaintiffs argued, *Panama Refining* compels the conclusion that they are likely to succeed on the merits.

II. Irreparable Harm

Plaintiffs argued irreparable harm both from the TCA's premarket review (PMTA) requirements and from the imminent revised enforcement policy to remove flavored products from the market, each of which is independently sufficient to support injunctive relief. *Plfs' Mem.* at 44-49.

The PMTA requirement imposes *current* burdens, given that no ENDS product may remain on the market past May 2020 unless a PMTA is submitted by the May deadline and accepted for filing by the FDA. Plaintiffs described in detail what FDA purports to require in a complete premarket review application, including clinical studies of human subjects, etc. The FDA's proposed final rule governing PMTAs expressly reiterates—as required under the TCA—that it will not accept an incomplete application. *See discussion at Plfs' Mem.* at 28. Plaintiffs argued that "they must begin paying lawyers and consultants and labs *now* in an attempt to assemble what they can in order to have something to submit by the deadline." *Plfs' Mem.* at 49 (emphasis in original).[2] Where governmental immunity bars any potential recovery of damages, "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Plfs' Mem.* at 45 (quoting *Texas v. U.S. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) (internal quotations omitted)). At least one USVA member has already engaged attorneys

[2] It is literally impossible to complete these studies for multiple reasons, including the fact that FDA has not even finalized the list of HPHCs for which testing is required, and, even if they finalize that list soon, there is insufficient time remaining to complete the required testing. *See Plfs. Mem.* at 28-29. FDA has not contradicted this evidence.

in an attempt to begin preparing PMTAs, ECF 15-7 ¶6(a)-(b) (Decl. of Tim Roberts) (who learned that insufficient time remained to complete required testing, even if he had started in August). Despite the apparent impossibility, outside of simply deciding to wind down one's business by May 2020, and in the absence of an injunction, Roberts and other USVA members must incur further compliance costs (time and money) in order to attempt to assemble something to submit to the FDA.[3] Plaintiffs have submitted several declarations affirming their intent to do so. Defendants have not attempted to controvert those declarations or Plaintiffs' summary of the PMTA burdens. Given that such compliance burdens are irreparable *per se*, as the Fifth Circuit has recognized, these compliance burdens alone satisfy this element in favor of Plaintiffs' motion.

As to the announcement of the imminent flavor ban, Defendants argue that Plaintiffs cannot raise this immiment injury because it has not yet occurred. This argument turns the process regarding preliminary injunctions on its head; the point of seeking a preliminary injunction is, ideally, to prevent the injury from occurring in the first place. *See Plfs' Mem.* at 44-45 (citing illustrative cases). Several USVA members explained in detail that they would be irreparably injured immediately upon announcement of the ban, and before it becomes effective, because they may be forced to hold a fire sale to extinguish inventory before the effective date. *See Plfs' Mem.* at 30-31. Defendants have not controverted this evidence. Plaintiffs have acted responsibly in seeking an injunction before the ban has been finalized, and the government's unilateral delay in finalizing it has allowed the parties to brief this issue without necessitating an absolute emergency for the Court. But that does not obviate the need to enjoin Defendants from banning Plaintiffs' products.

[3] Defendants seem to question this strategy; but given the impossibility, any prudent manufacturer would do this to try and stay in the market in hopes that the government will, once again, reverse or modify itself.

III. Public Interest

In their motion, Plaintiffs documented—based on the Defendants' own statements—that "what primarily causes death and disease from tobacco use isn't the nicotine" but "*the act of lighting tobacco on fire* to free that drug for inhalation," Plfs' Exhibit 2 (statement by then-FDA Com'r Gottlieb) (emphasis added), and that traditional cigarettes result in premature deaths of nearly *half a million* Americans every year. *See Plfs' Mem.* at 50. In the Deeming Rule itself, and in subsequent statements, the FDA has acknowledged the potential benefits of ENDS products in helping adults transition from deadly cigarettes. Due to these benefits, FDA extended the PMTA compliance deadline for ENDS to August 2022, and, in opposing the efforts by the plaintiffs in Maryland seeking to undo that extension, expressly argued that "[d]ramatically and precipitously reducing availability of these products could present a serious risk" that former smokers would return to burning deadly cigarettes, "*even if particular ENDS products ultimately receive marketing authorization and return to the market later*." *See id.* (quoting Decl. of M. Zeller, Director, Ctr. for Tobacco Products, U.S. FDA) (emphasis added). Granting the injunction plaintiffs seek here will prevent the "mass market exit" and "serious risk" feared by the FDA in July 2019. Defendants have not contradicted the veracity of the statements they made in July 2019.

Instead, Defendants argue that "the agency now believes that earlier and more substantial regulatory scrutiny of these products is warranted," citing an uptick in the incidence of youth vaping. *Defs' Mem.* at 42-43. Defendants' response only further illustrates that the public interest lies clearly on the side of granting a preliminary injunction.

First, the very fact that the FDA now cites a change in policy priority as to ENDS products only illustrates further that policy is being made on this subject at the complete whim of Executive

branch officials. These kinds of high-level policy judgments are vested with Congress alone under article I of the Constitution. Defendants write that Plaintiffs' reference to the "public interest in preserving the separation of powers" "begs the central question in this case," and they are correct. That is, as the Fifth Circuit has recognized, "[o]rdinarily … the protection of constitutional rights *would* be the highest public interest in a case," *Defense Distributed v. United States Dep't of State*, 838 F.3d 451, 458 (5th Cir. 2016). Therefore, the likelihood of success on the merits is an important consideration in the analysis of the public interest, and because Plaintiffs here are likely to succeed in establishing that the deeming provision unconstitutionally vests the Executive with legislative power, the public interest favors an injunction. That is, the FDA is not entitled to any deference with respect to its representation of the proper weighing of policy priorities regarding tobacco products or ENDS where their very authority to make those choices—unbound by Congressional guidance—is likely beyond constitutional bounds. *Burgess v. FDIC*, 871 F.3d 297, 304 (5th Cir. 2017) (holding that the public interest "does not weigh against a stay" because, in part, "the constitutionality of the structure of the fact-finding procedure on which the FDIC relies lies at the heart of this motion"); *Ironridge Glob. IV, Ltd. v. SEC*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015) ("it is never in the public interest for the Constitution to be violated"). The analysis of the public interest could end there.

But even if the Court proceeds to consider the FDA's representations supporting its changed policy priorities, and even if everything they claim were actually true (and it is not), it *still* does not support denying the injunction. The only issue at this stage is whether to temporarily delay FDA's authority until the merits can be resolved, and the Court should have no hesitation in doing so. It was *the FDA* that acted to delay the PMTA deadline for ENDS products until August 2022, and then argued *against* accelerating that deadline in the Maryland court. The FDA now

cites the need to address youth vaping with a flavor ban,[4] but has been in no hurry to do so. The intended flavor ban was announced more than two months ago, but still has not been released. The FDA responded to Plaintiffs' motion here on November 6, but even then could not commit itself to any anticipated date of announcement. Finally, last Friday (November 8), President Trump said that the Administration will "be coming out with something next week, very important on vaping,"[5] but then tweeted on Monday (Nov. 11):

> Will be meeting with representatives of the Vaping industry, together with medical professionals and individual state representatives, to come up with an acceptable solution to the Vaping and E-cigarette dilemma. Children's health & safety, together with jobs, will be a focus![6]

Apparently the Administration feels the need to now consult with additional stakeholders and experts before modifying its unilateral policy on ENDS products. In addition to further illustrating that legislative policy is being hammered out in the Executive branch rather than Congress, these continued delays and apparent modifications undermine any claim that there is an urgent need to implement whatever permutation of the flavor ban they are presently considering.

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[4] Defendants include only a passing reference to the recent spate of illnesses, and do not rely on same as evidence or rationale for its regulation. *See Defs' Mem.* at 2, 2 n.2 & 3. Their refusal to discuss these events beyond this throwaway reference is entirely appropriate, considering that their own Centers for Disease Control & Prevention has now confirmed that all 29 lung-tissue samples it has analyzed tested positive for vitamin E acetate. CDC, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products* (Nov. 8, 2019), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html. Vitamin E acetate is an additive linked to THC and black-market products, and not to legitimate vaping products such as sold by vape shops, as the CDC's update implicitly acknowledges. *See id.* ("CDC recommends that people should not: Buy any type of e-cigarette, or vaping, products, particularly those containing THC, off the street; Modify or add any substances to e-cigarette, or vaping, products that are not intended by the manufacturer, including products purchased through retail establishments."). If Defendants intended to claim that these vitamin E linked illnesses were implicated by legitimate vape products, they would have (and are required to have) cited actual evidence, given that they are the ones with the access to the actual evidence.

[5] ABC News, *White House says to expect announcement of ban of flavored vape products next week* (Nov. 8, 2019), at https://abcnews.go.com/Politics/white-house-expect-announcement-ban-flavored-vape-products/story?id=66763834.

[6] ABC News, *Trump signals flexibility on plans to ban flavored vaping products amid pushback from industry* (Nov. 11, 2019), at https://abcnews.go.com/Politics/trump-signals-flexibility-plans-ban-flavored-vaping-products/story?id=66926780.

See Cigar Assoc. of Am. v. FDA, 317 F. Supp. 3d 555, 563 (D.D.C. 2018) ("That there is no immediate public interest is reinforced by the fact that Defendants are considering rulemaking that might alter the warnings requirements as to premium cigars, a key covered product.").

Remarkably, in attempting to reconcile the planned flavor ban with the dire warnings voiced by Dr. Zeller just four months ago, the FDA points to *JUUL*'s purported intent and ability to submit a PMTA and remain on the market. *Defs' Mem.* at 43-44. JUUL is the most popular of the cartridge-based e-cigarettes and has almost single-handedly fostered the increase in youth vaping that the FDA purports to want to address. Former Commissioner Gottlieb has been clear about this, stating on Nov. 7 that "[t]he biggest drivers of youth e-cig use are the access and appeal to kids. This access is largely through convenience store sales. The appeal is to cheap, disposable, high nicotine, and pod or cartridge based e-cigs, **especially Juul. Juul is #1 preferred brand of American children**." **Exhibit 19**.[7] On Nov. 11, he said "Juul really is single-handedly almost destroying this opportunity" of e-cigarretes to help addicted adult smokers quit traditional cigarettes. **Exhibit 20**. (The 76% market share for Juul cited by Defendants is based solely on *convenience store* sales, and does not include sales in vape shops, such as the USVA members' shops.) Gottlieb stated that "kids just don't like those big open-tank contraptions," *i.e.*, the "open-tank vaping systems that are sold in the adult vape shops," which he advocates "preserv[ing] for adults."[8] These statements are corroborated by studies.[9]

[7] While these statements were made after Gottlieb's government service, the Court remains free to consider them over any potential hearsay objection in the context of a preliminary injunction. *See Plfs' Mem.* at 32 (citing cases).

[8] STAT, *Former FDA commissioner calls for a full ban on pod-based e-cigarettes* (Nov. 12, 2019), https://www.statnews.com/2019/11/12/gottlieb-ban-pod-based-e-cigarettes/.

[9] *See, e.g.*, Cullen, et al., e-Cigarette Use Among Youth in the United States, 2019 (reporting that Juul is the preferred brand of nearly 60% of high school e-cigarette users), at https://jamanetwork.com/journals/jama/article-abstract/2755265.

Ironically, therefore, FDA has identified an additional reason that the injunction serves the public interest: in the absence of an injunction, JUUL will effectively enjoy a government-created monopoly, while the open-system devices preferred by adult vapers will be wiped out.

Any way the Court looks at it, an injunction serves the public interest. Such a temporary order would do no harm to the Defendants, yet would prevent irreparable and permanent damage to Plaintiffs. *See Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1305 (2010) (Scalia, J., *in chambers*). Moreover, the fact that the Government now seeks to rush Plaintiffs' products off the market, reversing the position it held only four months ago, *including by applying a PMTA deadline for which the application requirements are not even finalized*, is a "grossly unfair exercise of agency authority." *Cigar Assoc. of Am.*, 317 F. Supp. 3d at 563 ("[T]he FDA's insistence that the cigar industry, as a whole, meet the August 10, 2018, effective date, while the agency seeks additional information that bears on the need for health warnings on premium cigars is a grossly unfair exercise of agency authority.") (internal quotation omitted).

To the extent there is a legitimate need for regulatory action, Congress can direct it. The requirements of the Constitution are not suspended simply because an FDA official, or even the President, waxes or wanes one way or another as to the need for an "urgent" flavor ban.

IV. No Unreasonable Delay

While a long delay *may* be an *indication* that a plaintiff is *not suffering irreparable harm*, *Opulent Life Church v. City of Holly Springs*, Miss., 697 F.3d 279, 297 (5th Cir. 2012), Plaintiffs have not delayed in seeking relief, and their evidence clearly establishes irreparable harm. As in *Opulent Life Church*, to the extent there has been any delay here, it was due to the Defendants' own actions. The FDA has consistently failed to provide Plaintiffs and other industry participants notice of what will actually be required of them. FDA has still yet to even provide binding

guidance and only released its *proposed* final rule on September 20, 2019 (after Plaintiffs' suit was filed). Doc. 17 at 25. Further, it was not until after Plaintiffs' Complaint was filed that the Executive branch announced on September 11, 2019, that it intended to implement the additional flavor ban. *Id.* at 26. Once this ban was announced, Plaintiffs would only have a 30-day window until all (non-tobacco) flavored e-liquids were removed from the market. *Id*. While the FDA claimed on September 20, 2019, that it intended to finalize this plan in the "coming weeks," it still has not done so. *Id.* at 27. Given this, Defendants' argument seems to be that a complaint and request for preliminary relief filed shortly after the PMTA deadline was accelerated by 27 months, and yet prior to any formal binding guidance on either the PMTA process or the "flavor ban," constitutes a "long delay." To the contrary, Plaintiffs acted responsibly, and the Defendants' delay argument is in direct tension with its argument that Plaintiffs' challenge to the coming flavor ban is not even ripe. *Opulent Life Church*, 697 F.3d at 297.

PRAYER

For the foregoing reasons, and for any further reasons appearing after any hearing on this motion, Plaintiffs respectfully request that the Court preliminarily enjoin Defendants from exercising any authority over any "tobacco products" deemed to be subject to the TCA pursuant to Defendants' power under § 387a(b) of the TCA, including, but not limited to, the current Deeming Rule and any enforcement of same. Plaintiffs further request that the Court waive the bond requirement, and Defendants have not opposed such request.

Respectfully submitted,

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Counsel for Plaintiffs

Certificate of Service

I do hereby certify that I have electronically served the foregoing Reply using the Court's ECF system, which sent notification to all known counsel of record.

THIS, the 13th day of November, 2019.

/s/ *Spencer M. Ritchie*
Spencer M. Ritchie